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10/065,159	09/23/2002	John Eric Tkaczyk	RD-28334	4870

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EXAMINER	
NGUYEN, TRAN N	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/065,159	TKACZYK ET AL.	
	Examiner	Art Unit	
	Tran N. Nguyen	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/23/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Notice to Applicant

1. This communication is in response to the communication filed 09/23/2002. The set of pending claims is as follows: 1-40.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 09/23/2002 is entered and considered by Examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim(s) 1-3, 6-9, 13, 17-19, 22-25, 29, 33, 36-38 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (6196970).

(A) As per claim 1, Brown discloses a method (Figure 2a label 200) and a system (Figure 1 label 100) capable analyzing research data collected during the course of research testing (It is noted that analyzing research data collected during the course of research testing is considered to be "managing clinical study information", wherein Brown discloses research testing to be a clinical trial (column 1 line 13 to column 3 line 10) or study (column 3 line 60)),

wherein the method and system is capable of being utilized by a set of medical research experts (column 5 line 15, Figure 1 label 121),

wherein the system (Figure 1 label 100) is comprised of:

(a) a server device (Figure 1 label 130) coupled to a database (column 5 line 4, Figure 1 label 132) (It is noted that the server device is considered to be "a server system", and the database is considered to be "a centralized database");

(b) a plurality of medical research expert devices and research subject devices coupled to the system (column 5 line 4, Figure 1 label 120, 110) (It is noted that the plurality of medical research expert devices and research subject devices are considered to be "at least one client system");

(c) wherein the database contains therein a protocol (column 6 line 9-11, Figure 1 label 131, Figure 2a label 204) (It is noted that the protocol is considered to be "a plurality of templates");

the method comprising:

(a) receiving of research information by the server device (column 6 line 5-8, Figure 2a label 203), wherein the research information comprises the type of data to be collected from a set of subjects (column 6 line 1-4, Figure 2a label 202), and wherein the research information is entered through the medical research expert device along with the protocol (It is noted that entering research information along with the protocol into the medical research expert device is considered to be "the CS information entered through a user selected template displayed on the client system");

(b) recording the research information into the database by the server device (column 6 line 9-11, Figure 2a label 204);

(c) presenting the research information and protocol to a set of research subjects (Figure 2a label 205-206) and allowing the subjects to respond (Figure 2a label 207-208) (It is noted that presenting research information and protocol to the research subjects and allowing the responses thereto is considered to be "tracking CS information stored in the centralized database");

(d) recording the responses in the database (Figure 2a label 209-210), wherein the steps in (c) and the recording step are repeated until the protocol is complete (Figure 2b label 221) (It is noted that repeating the steps in (c) and the recording step until the protocol is completed is considered to be "updating the centralized database periodically with newly received CS information to maintain CS information");

(e) providing the information to interested parties (column 6 line 52-54, column 7 line 29-30).

(B) As per claim 2, Brown discloses the method of claim 1, further comprising:

(a) aggregating, statistically analyzing, and sending from the server device to the medical research experts the information received from the research subject devices (column 6 line 45-51, Figure 2a label 211-212) (It noted that aggregated and analyzed information is considered to be "at least one report summarizing CS information and findings for a clinical study". It is also inherent

that the medical research experts interact with the system via the medical research expert devices).

(C) As per claim 3, Brown discloses the method of claim 1, further comprising:

(a) aggregating, statistically analyzing, and sending from the server device to the medical research experts the information received from the research subject devices (column 6 line 45-51, Figure 2a label 211-212), wherein the information is received from at least one research subject (Figure 1 label 111, Figure 2a label 205-210) (It noted that a research subject is considered to be "at least one patient involved in a clinical study").

(D) As per claim 6, Brown discloses the method of claim 1, wherein receiving research information comprises:

(a) determining and sending research information and protocol to the subject (Figure 2a label 205) (It is inherent that at least a portion of the protocol selected by the medical research expert is sent to the subject to provide the subject with instructions to operate the medical device, as discussed below);

(b) displaying the information received in (a) to the subject (column 6 line 18-23, Figure 2a label 206, Figure 1 label 112);

(c) responding to the protocol with data from the patient's medical device (column 4 line 9-12) (It is noted that data from the patient's medical device is considered to be "utilized medical equipment information").

Insofar as the remainders of the limitations of claim 6 are concerned, Brown need not disclose these limitations in view of the limitation "at least one of".

(E) As per claim 7, Brown discloses the method of claim 1, wherein presenting the protocol to subjects for response comprises:

(a) responding to the protocol with data from the patient's medical device (column 4 line 9-12) (It is noted that data from the patient's medical device is considered to be "utilized medical equipment information"), aggregating and analyzing the data (Figure 2a label 211) (It is noted that aggregating and analyzing data is considered to be "compiling a data report");

(b) sending the information received from the subjects to the various medical research experts (column 6 line 47-50, Figure 2a label 212) (It is noted that the various research experts are considered to be "a predesignated party").

(F) As per claim 8, Brown discloses the method of claim 1, wherein presenting the protocol to subjects for response comprises:

(a) evaluating the information by the protocol, and updating the information according to protocol logic as appropriate (column 6 line 55-60, Figure 2a label 213-214) (It is noted that a protocol residing on a server device is considered to be "at least one computer program").

(G) As per claim 9, Brown discloses the method of claim 1, wherein presenting the protocol to subjects for response comprises:

(a) responding to the protocol with data from the patient's medical device (column 4 line 9-12) (It is noted that data from the patient's medical device is considered to be "utilized medical equipment information");

(b) sending the information received from the subjects to the various medical research experts (column 6 line 47-50, Figure 2a label 212).

Insofar as the remainders of the limitations of claim 9 are concerned, Brown need not disclose these limitations in view of the limitation "at least one of".

(H) As per claim 13, Brown discloses the method of claim 1, further comprising:

(a) connecting the research subject devices and the medical research expert devices to the server device via a communications network (Figure 1 label 140), wherein the network connects remote devices (Abstract) (It is noted that a network connecting remote devices is considered to be a "wide area network").

Insofar as the remainders of the limitations of claim 9 are concerned, Brown need not disclose these limitations in view of the limitation "includes one of".

(I) Claims 17-19, 22-25, and 29 recite a system capable of performing the method of claims 1-3, 6-9, and 13, respectively. It is noted that the scope of

claims 17-19, 22-25, and 29 is substantially enveloped within the scope of claims 1-3, 6-9, and 13.

Therefore, claims 17-19, 22-25, and 29 are rejected under the same rationale as applied to claims 1-3, 6-9, and 13 above, and incorporated herein.

Specifically, the output element of the research subject device (Figure 1) capable of displaying portions of the protocol (Figure 2a) is considered to be "a browser".

(J) Claims 33, 36-38 recite a computer-readable medium containing software thereon, such that when the instructions contained therein are executed by the computer's processor, the functionality of the software is realized in the form of the method as recited in claims 1-3, 6-9.

It is noted that the scope of claims 33, 36-38 is substantially enveloped within the scope of claims 1-3, 6-9. See MPEP 2106.01(I). Therefore, claim 33, 36-38 are rejected for at least the same rationale as applied to claim 1-3, 6-9, and incorporated herein.

Specifically, the limitations "adding" and "deleting" data within a database is substantially enveloped by the limitation "updating".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

> be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4-5, 14-16, 20-21, 30-32, 34-35 are rejected under 35 U.S.C. 102(b) as anticipated by Brown or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brown in view of Goldwasser (4737921).

(A) As per claim 4, Brown discloses coupling a plurality of medical appliances to the system (column 5 label 11-13, Figure 1 label 114, column 6 line 27-36, Figure 2a label 207), wherein the plurality of medical appliances comprises a location sensing device and a digital video camera (column 6 line 35) (It is noted that a location sensing device and a digital video camera is considered to be "a computed tomography device").

Insofar as the limitations "a radiography device", "a positron emission tomography device", and "an ultrasound imaging device" are concerned, Brown need not disclose these limitations in view of the limitation "at least one of".

Notwithstanding the above, Goldwasser discloses that using medical devices for medical research (column 2 line 48 to column 3 line 2), wherein the medical devices comprise computed tomography imaging technique (column 1 line 23-39), X-rays (column 1 line 17), PET (column 2 line 2), and ultrasound (column 2 line 14-16), is well known in the art.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Goldwasser within the invention as described by the disclosure of Brown with the motivation of sending additional data to the server (Brown; column 5 line 11-14), providing knowledge and information of the structure and condition of a patient's internal anatomy (Goldwasser; column 1 line 10-22), and facilitating medical research (Goldwasser; column 2 line 67 to column 3 line 1).

(B) As per claim 5, Brown discloses receiving research information, comprising:

(a) determining and sending research information and protocol to the subject (Figure 2a label 205) (It is inherent that at least a portion of the protocol selected by the medical research expert is sent to the subject to provide the subject with instructions to operate the medical device, as discussed below);

(b) displaying the information received in (a) to the subject (column 6 line 18-23, Figure 2a label 206, Figure 1 label 112);

(c) coupling the medical appliance to the port of the subject device in response to the protocol (column 6 line 26-30) (It is noted that coupling the

medical appliance in response to the protocol is considered to be "operating the at least one medical device based on the entered protocols");

(d) receiving by the server device information sent from the subject device (Figure 2a label 208-210), wherein the information sent comprises data from a digital video camera (column 6 line 35) (It is noted that data from a digital video camera is considered to be "diagnostic images").

Insofar as the limitation "x-rays" is concerned, Brown need not disclose this limitation in view of the limitation "at least one of".

Notwithstanding the above, Goldwasser discloses that using medical devices for medical research (column 2 line 48 to column 3 line 2), wherein the medical devices comprise X-rays (column 1 line 17), is well known in the art.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Goldwasser within the invention as described by the disclosure of Brown with the motivation of sending additional data to the server (Brown; column 5 line 11-14), providing knowledge and information of the structure and condition of a patient's internal anatomy (Goldwasser; column 1 line 10-22), and facilitating medical research (Goldwasser; column 2 line 67 to column 3 line 1).

(C) Claims 14-16 recite various combinations of steps as recited in claims 1-6. It is noted that the scope of claims 14-16 is substantially enveloped within the scope of claims 1-6.

Therefore, claims 14-16 are rejected under the same rationale as applied to claims 1-6 above, and incorporated herein.

(D) As per the set of claim(s): 20, 21, 30, 31, 32, 34, 35, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 4, 5, 30, 31, 32, 4, 5, respectively, and incorporated herein.

7. Claim(s) 10-11, 26-27, 39-40 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Rice (2002/0042723).

(A) As per claim 10, Brown discloses the method of claim 10, wherein providing the information to interested parties comprises:

(a) storing research information in the database, the information comprising information received from the subjects (column 7 line 29-30) (It is noted that it is inherent that the information comprises a list of patients).

Brown does not disclose inquiring about a specific patient.

Rice discloses correlating FDA alerts with patient data (Abstract), wherein a list of patients is displayed (Figure 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rice within the invention as described by the disclosure of Brown with the motivation of alerting doctors and nurses of patients who are affected by the FDA alerts (Rice; paragraph 0007),

and preventing patient deaths by failing to respond to incoming data in real time (column 2 line 45-67).

(B) As per claim 11, Brown discloses the method of claim 10, wherein providing the information to interested parties comprises:

(a) storing research information in the database, the information comprising information received from the subjects (column 7 line 29-30) (It is noted that it is inherent that the information comprises a list of patients).

Brown does not disclose inquiring about a specific patient.

Rice discloses correlating FDA alerts with patient data (Abstract), wherein a list of patients is displayed (Figure 3). Rice further discloses displaying an FDA alert pertaining to patient weight (Figure 4).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rice within the invention as described by the disclosure of Brown with the motivation of alerting doctors and nurses of patients who are affected by the FDA alerts (Rice; paragraph 0007), and preventing patient deaths by failing to respond to incoming data in real time (column 2 line 45-67).

Insofar as the remainders of the limitations of claim 11 are concerned, Brown and Rice need not disclose these limitations in view of the limitation "at least one of".

(C) As per the set of claim(s): 26, 27, 39, 40, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 10, 11, 10, 11, respectively, and incorporated herein.

8. Claim(s) 12, 28 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of official notice.

(A) As per claim 12, Brown discloses providing the information to interested parties (column 6 line 52-54, column 7 line 29-30), wherein the information is stored in the database (column 7 line 29-30).

Brown does not disclose accessing, searching, or retrieving data from the database for display; however, official notice is taken that:

(a) forming a query;

(b) transmitting the query to the a database;

(c) parsing of the query by the database;

(d) retrieving information stored in the database as indicated by the result of (c);

(e) returning the result of (d) for display;

is old and well established in the art of database.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to search the database of Brown as discussed above with the motivation of obtaining the data contained therein.

(B) As per the set of claim(s): 28, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 12, respectively, and incorporated herein.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

(A) Lamb (Bridging the Gap between Drug Discovery and Market) discloses contracted research organizations (page 1).

(B) Briegs (7054823) discloses a system for designing and monitoring clinical trials (Abstract).

(C) Colon (5991731) discloses a method for managing data used in conducting clinical studies concerning remote subjects (Abstract).

(D) Michelson (20020002474) discloses an online collaboration tool for clinical research participants (Abstract).

(E) Hetzel (20020029155) discloses a process and system capable of managing medical clinical trials (Abstract).

(F) Reitberg (20020032581, 20020038310, 20020192159) discloses a method of evaluating and/or optimizing outcomes for a single-patient drug trial (Abstract).

(G) Huyn (20020035486) discloses a clinical questionnaire capable of dynamically generating questions (Abstract).

(H) Knight (20020099570) discloses techniques for recruiting patients into a clinical trial (Abstract).

(I) Drazen (20020120471) discloses a system and method capable of storing a plurality of medical guidelines for research (Abstract).

(J) Shiffman (20020143577) discloses a system capable of predicting subject compliance (Abstract).

(K) Banta (20020188475) discloses a method of merging two clinical studies for a single patient (Abstract).

(L) Kozam (6496827) discloses a system capable of storing remote clinical research data in a centralized location.

(M) Lau (20020198739) discloses a system and method capable of mapping clinical data to a predetermined standard (Abstract).

(N) Bleicher (6820235) discloses a system and method capable of managing clinical trial data (Abstract).

(O) Schmidt (6839678) discloses a system capable of conducting a plurality of clinical studies.

Any inquiry concerning this communication or earlier communications from Examiner should be directed to Tran N. Nguyen (Ken) whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, Examiner's Supervisor, Joseph Thomas can be reached on (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TN
05/30/2007

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